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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/229,751 | 01/14/1999 | CHARLES L. TURNBOUGH | | 5473 |

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| EXAMINER |
| WESSENDORF, TERESA D |

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| ART UNIT | PAPER NUMBER |
| 1639 | |

DATE MAILED: 01/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/229,751

Applicant(s)

TURNBOUGH, CHARLES L.

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-14, 16-20 and 22-27 is/are pending in the application.
- 4a) Of the above claim(s) 1-9, 14, 16, 17, 19, 20, 23 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-13, 18, 22, 24, 26 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

Claims 1-9, 11-14, 16-20, 22-27 are pending in the instant application.

Claims 1-9, 14, 16, 17, 19, 20, 23 and 25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claims 10, 15 and 21 have been cancelled.

Claims 11-13, 18, 22, 24, 26 and 27 are under consideration.

Specification

The objection to disclosure has been overcome with the amendments to the specification.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 11-13, 18 and 21-24 and 26-27 are rejected under 35 U.S.C. 101 because the claimed composition is drawn to non-statutory subject matter.

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The rejection under this statute has been obviated with the amendment to the claim.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-13, 18, 21-24 and 26-27 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure, which is not enabling. A composition comprising of a peptide ligand having the different peptide sequences (e.g., TSQNVRT) identified by a phage method in the disclosure that binds to a bacterial spore with a carrier is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976) for reasons set forth in the last Office action.

Response to Arguments

Applicants appear not to appreciate the rejection. Applicants question whether the examiner means that the sequence of amino acids is not known in the art. It is urged that the

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independent claims clearly claim the most preferred sequence (TSQNVRT), as well as other preferred sequences. It is argued that the examiner also urges that the specification fails to teach how to make a composition comprising of a sample suspected to contain a bacterial spores. The invention does not require making a sample containing an anthrax any more than one makes sugar to do a blood sugar test. The sample being tested is placed in an environment to see if organisms are present. See page 15. The making of supports with indicators is so common as to be known to any skilled in the art.

In reply, the rejection is not based on the amino acid being not known in the art. Rather, that the specification discloses the components of the composition comprising the peptide sequences (as the active ingredient) with the carrier. The claim drawn to a composition comprising of a purified peptide ligand **and a sample suspected of containing spores which bind to said peptide ligand** goes against the conventional way of claiming a composition (in the prior art and specification). As referred to by applicants, page 15 of the instant specification discloses the conventional way of a composition claim. That is, a composition comprising of a purified peptide, formulated with a pharmaceutically acceptable carrier, such as buffered saline. This composition is used for administration to animals to elicit

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an immune response or to bind to the spore to cause alteration in the spore pathogenicity. The instant claim is however, so confusing. The sample, in and of itself, would be considered a crude composition. The specification fails to teach how to make a composition comprising of a sample suspected to contain a bacterial spore. It is not apparent from the disclosure the determination of how a sample is suspected to contain a spore and a tagged peptide ligand and the means by which a tagged peptide binds to said spore. The disclosure is unclear with respect to the exact components present in a sample to make a composition comprising said sample and a tagged peptide sequence. See Grow (U.S. 6,040,191) particularly at col. 5, lines 2 [The invention appears to reside in a modified biopanning method that identifies a peptide ligand from a library that binds specifically to the disclosed bacterial spores.]

Applicants have not addressed the rejection with respect to the specification failing to teach how to make and use a peptide ligand with any 5-12 mers peptide sequences. The specific peptide obtained from the specification does not provide an enabling disclosure for the 5-12 of undefined sequences containing every conceivable amino acid residues, modified or unmodified. Also, the binding ability of the peptide to bind to

a spore in a sample. Since applicants have not addressed this rejection, it is believed that applicants are acquiescing therewith.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-13, 18, 21-24 and 26-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons advanced in the last Office action.

Response to Arguments

A. Applicants urge that claims are read in light of the description. A composition must have those components listed. However, it is customary to identify only those components that are required. The claims are to compositions.

In response, as read in light of the disclosure, specifically the cited page 15, there is no description of a composition containing a sample and a purified peptide ligand. While the other ingredients in a composition need not be

identified however, the main component has to be identified. Thus, it is unclear, as read in light of the disclosure, as to a composition containing the combination of a sample **suspected** of containing an ingredient and another ingredient.

B. It is argued that any one skilled in the art that is at all acquainted with anthrax knows that the support would be placed in the environment suspected of having anthrax organisms present.

In reply, applicants' argument is not commensurate in scope with the claim. Claim 12 recites binding the peptide ligand with a support, and not the support just being present in the environment?

C. and D. Applicants have not addressed the rejection under these paragraphs. Since applicants failed to address the rejections, then it is believed that applicants are acquiescing therewith.

E. Applicants urge that one having ordinary skill in the art knows what a sponge or tape is.

In reply, it is not the definition of a sponge or tape that is at issue. Rather, it is unclear to its use in the composition comprising a sample suspected of having a spores and a peptide ligand, especially in the absence of positive support in the specification.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 21 is rejected under 35 U.S.C. 102(b) as being anticipated by applicants' disclosure of known prior art. [This rejection is based on B. subtilis. The search has been extended since there is no prior art for the elected peptide sequence, TSQNVT, SEQ. ID. 40] for reasons set forth in the last Office action.

Response to Arguments

It is argued that there is no teaching in the art to show that any sequence of 5 to 12 mers should be placed in a sample suspected of containing spores.

In reply, applicants' arguments are not commensurate in scope with the claims. The claims do not recite placing the 5-12 mers in a sample suspected of containing spores. Rather, the claim recites a composition. The prior art

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discloses said composition of 5-mer i.e., NHFLP... that attaches to a receptor on the spore surface.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-13, 18, 21-24 and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ezzell et al (Jrnl. of Clinical Microbiology) in view of D'Mello (Virology) for reasons advanced in the last Office action.

Response to Arguments

Applicants argue that Ezzell teaches a composition comprising a monoclonal antibody (much larger protein) and D'Mello suggests a ligand binding to a monoclonal antibody not a spore. Neither suggests in any way the use of ligands of 5-12-mer that bind to spores. Regarding the rejection of claim 11, that a polymeric support is known for ligands binding to an

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antibody has nothing to do with small peptides which bind to spores.

In reply, applicants' used of the word comprising does not limit the peptide sequence to only 5-7 amino acid residues. Comprising is an open-ended language. Attention is directed to Ezzell, particularly, page 223, abstract; page 226, col. 1 up to page 228, col. 1 which discloses a composition comprising a peptide ligand i.e., a monoclonal antibody that binds to Bacillus spores and a sample suspected of containing said Bacillus spores. D'Mello is employed not for the purpose as argued. Rather for the motivation derived in using fragments of an antibody in a composition, as set forth in the last Office action. Accordingly, the combined teachings of the prior art would lead one having ordinary skill in the art to the claimed composition.

Regarding, claim 11 if a polymeric support can bind to a small molecule, as 5-7 mer peptide, it is not clear how a known support, as admitted by applicants, can not be extrapolated to a larger molecule as antibody.

As stated in the last Office action, claim 23 (elected peptide sequence of SEQ. ID. 40 that binds to B. anthracis spore) and claim 24 are free of prior art i.e., in a composition comprising of said sequences and a carrier, not a sample.

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

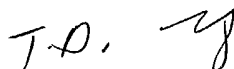
This application contains claims 1-9, 14, 16, 17, 19, 20, 23 and 25 drawn to a non-elected invention. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
January 16, 2004